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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/760,807 | 01/17/2001 | Maria Palasis | 12013/58101 | 4398 |

26646 7590 07/24/2002

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[REDACTED]
EXAMINER

THANH, LOAN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3763 | |

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/760,807 | PALASIS, MARIA | |
| | Examiner LoAn H. Thanh | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 May 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The claim rejection under 35USC 112, 2nd rejection has been obviated in view of the amendment filed 05/16/2002.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the grooved material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The amendment filed 5/16/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: grooved material (claim 19).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague because it is unclear what applicant intended by a grooved material. The Examiner is taking the position that all materials would have some variability in during manufacturing to have some degree of grooves in the material no matter how smooth it appears.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 12-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Dror et al. (U.S. Patent No. 5,102,402).

Dror et al. disclose a balloon catheter having a therapeutic material on the exterior surface. See figs. 1-10 and col. 2.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application

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published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,3, 5, 7,9, 12-14,16-17, 20-21, 24-25 are rejected under 35

U.S.C. 102(e) as being anticipated by Davis et al. (U.S. Patent No. 6,132,397).

Davis et al. disclose a system for delivering therapeutic agent having a balloon catheter having an internal lumen and a second internal lumen (72). See figs. 2-16. The device as claimed is capable of performing the intended use. The outer surface of the balloon is considered to be in communication with the therapeutic material when the balloon is in the expanded state via the distal opening of the lumen (72).

Claims 1-6,11-18,20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Abiuso et al. (U.S. Patent No.5,213,576) .

Abiuso et al. discloses a balloon catheter having first and second/dilatation bladder/balloon. See figs. 1-8 and abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dror et al. or Abiuso et al. in view of Slepian (U.S. Patent No. 5,662,609) .

Dror et al. or Abiuso et al. teach all the limitations of the claims. However, they are silent to the materials of the balloon. Slepian teaches the balloon material to be silicone or latex in the analogous art of balloon catheters for delivering therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of the balloon of Dror et al. or Abiuso et al. with materials of Slepian in order to provide the desired elasticity property.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dror et al. or Abiuso et al. in view of Shapland et al. (U.S. Patent No. 5,286,254) .

Dror et al. or Abiuso et al. teach all the limitations of the claims. However, they are silent to the materials of the balloon. Shapland et al. teach the balloon material to be silicone or polyurethane in the analogous art of balloon catheters for delivering therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of the balloon of Dror et al. or Abiuso et al. with materials of Shapland et al. in order to provide the desired elasticity property.

Response to Arguments

Applicant's arguments filed 5/16/2002 have been fully considered but they are not persuasive. With respect to applicant's arguments on page 7-8 of the amendment, applicant is referred to the embodiment of figs. 5,7-8 and 10 of Dror et al.

In response to applicant's argument that the limitation of the balloon replicates the irregular interior vessel surface, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant is directed to figs. 7-5 and 10 wherein the therapeutic material is shown in different embodiments where Dror et al. show the therapeutic material to be on the outer surface of the balloon. Further, fig. 2 shows an irregular interior vessel surface. At a point in time the balloon will encompass the space in that vessel. With respect to claim 13, applicant is directed to figs. 8 and 10 of Dror et al.

With respect to the Davis et al. and Abuiso et al. reference, applicant appears to be arguing intended use. See above. Further, during expansion it is capable of filling the interior of the irregular vessel. Since Abuiso et al. teaches the balloon to be flexible, it is capable of performing the function. Without any further distinguishing structural features, the Examiner is maintaining her position.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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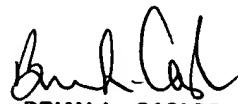
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LoAn H. Thanh
Examiner
Art Unit 3763

LT
July 22, 2002



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700